DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

FOOD AND DRUG ADMINISTRATION

[21 CFR PART 310]

[DOCKET NO. 75N-0151]

40FR52049

PROPOSAL TO AMEND PROCEDURES FOR DENYING OR REVOKING APPROVAL OF APPLICATIONS TO RECEIVE SHIPMENTS OF METHADONE

Pub 11/7/75

The Commissioner of Food and Drugs is proposing to amend the hearing procedures in the methadone regulations to provide for a separation of functions between the Bureau of Drugs and the Office of the Commissioner concerning denial or revocation of approval of an application to receive shipments of methadone, and to describe the requirements of a notice of opportunity for hearing and the procedures governing a request for hearing. Interested persons have until (insert date 60 days after date of publication in the FEDERAL REGISTER) to submit comments.

The Commissioner, by an order published in the FEDERAL REGISTER of March 13, 1974 (39 FR 9750), promulgated regulations revising, among other provisions, § 314.200 (21 CFR 314.200) concerning the requirements of a notice of opportunity for hearing, request for hearing, and grant or denial of hearing applicable to new drug applications. The primary purpose of that revision was to implement four 1973 Supreme Court decisions that intrepreted the new drug provisions of the Federal, Food, Drug, and Cosmetic Act. The principal changes made were in the separation of functions between the Commissioner and the Director of

75-473

75N-0151

N1

the Bureau of Drugs concerning the notice of opportunity for hearing and the granting or denying of a request for hearing, and in the development of procedures for summary disposition of hearing requests by the Commissioner.

In the preamble to the order of March 13, 1974, the Commissioner recognized that, while the former procedures had been upheld in the courts, modification of the hearing procedures to separate sharply the functions of the Commissioner and the Director of the Bureau of Drugs was desirable to dispel any perception of prejudgment and unfairness that arises from having the same person who issues the notice of opportunity for hearing rule on whether a hearing is justified. Therefore, the Director of the Bureau of Drugs, by an order published in the same issue of the FEDERAL REGISTER (39 FR 9657), was delegated the authority to issue a notice of opportunity for hearing (21 CFR 2.121(1)). If a request for hearing is made, the Commissioner then reviews, without Bureau of Drugs participation, both the request for hearing and a proposed order ruling on the matter, drafted by the Bureau of Drugs. After his review, the Commissioner issues a FEDERAL REGISTER notice granting or denying the hearing.

The Commissioner concludes that the hearing procedures in § 310.505(h) of the methadone regulations should be amended to conform to the hearing procedures applicable to new drug applications in § 314.200. This revision will effectuate the policy of the Commissioner to separate the functions of the Director of the Bureau of Drugs and the Commissioner in issuing a notice of opportunity for a hearing and in granting or denying a request

for a hearing. However, the Commissioner believes that the informal conference currently provided in the methadone regulations (21 CFR 310.505(h)(2)) is advantageous and should be retained. This conference will now be conducted by the Director of the Division of Methadone Monitoring who will make a recommendation to the Director of the Bureau of Drugs concerning the application. If the latter finds that the applicant has failed to submit adequate assurance justifying approval of the application, he shall issue a notice of opportunity for hearing.

Currently, § 310.505(h) provides that when it is found that an applicant fails to submit adequate assurance justifying approval of his application to receive shipments of methadone (hereinafter referred to as methadone application), a notice of opportunity for hearing should be published and all matters thereafter be handled in accordance with the procedures and requirements contained in § 314.200. However, since § 314.200 contains certain provisions that are not applicable to methadone applications, the Commissioner concludes that this reference may lead to uncertainty with regard to the type of notice required for a notice of opportunity for hearing on a methadone application, as well as the

requirements for a request for hearing. He, therefore, has amended the methadone regulations by excerpting from § 314.200 the hearing procedures and those requirements relevant to a request for hearing on a methadone application, and has incorporated them into a new paragraph specifically applicable to methadone applications. Thus, the procedures set forth in § 314.200 remain essentially unchanged.

The Commissioner advises, however, that the 60-day time period provided for by § 314.200 to file records and information to justify a hearing is not appropriate for this regulation. While a 60-day period is proper when broad scientific issues of drug safety or effectiveness are involved, it is neither necessary nor appropriate to the limited factual issues involving the conditions for use of methadone by individual treatment programs. Therefore, the Commissioner proposes to require that both the request for a hearing and all filings in support thereof be submitted within 30 days, with a hearing, when justified, to be held no more than an additional 90 days after the expiration of the initial 30-day time period provided.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 701(a), 52 Stat. 1052-1053, as amended, 1055 (21 U.S.C. 355, 371(a))); the Public Health Service Act as amended (sec. 303(a), 70 Stat. 929, as amended (42 U.S.C. 242a(a))); the Comprehensive Drug Abuse Prevention

and Control Act of 1970 (sec. 4, 84 Stat. 1241 (42 U.S.C. 257a)), and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend § 310.505 by revising paragraph (h), and by adding a new paragraph (1) to read as follows:

§ 310.505 Conditions for use of methadone.

* * * * *

(h) Denial or revocation of approval. (1) Complete or partial denial or revocation of approval of an application to receive shipments of methadone (Forms FD-2632 "Application for Approval of Use of Methadone in a Treatment Program" and FD-2636 "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Maintenance Treatment") may be proposed to the Director of the Bureau of Drugs, Food and Drug Administration, by the Director of the Division of Methadone Monitoring, Bureau of Drugs, on his own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute on Drug Abuse, the State authority, or any other interested person.

(2) Before presenting such a proposal to the Director of the Bureau of Drugs, the Director of the Division of Methadone Monitoring will notify the applicant in writing of the proposed action and the reasons therefor and will offer him an opportunity to explain the matters in question in an informal conference and/or in writing within 10 days

after receipt of such notification. The applicant shall have the right to hear and to question the information on which the proposal to deny or revoke approval is based, and may present any oral or written information and views.

(3) If the explanation offered by the applicant is not accepted by the Bureau of Drugs as sufficient to justify approval of the application, and denial or revocation of approval is therefore proposed, the Director of the Bureau of Drugs will evaluate information obtained in the informal hearing before the Director of the Division of Methadone Monitoring. If the Director of the Bureau of Drugs finds that the applicant has failed to submit adequate assurance justifying approval of the application, he shall issue a notice of opportunity for hearing with respect to the matter pursuant to paragraph (1) of this section, and the matter shall thereafter be handled in accordance with the procedures therein.

(4) If the Secretary determines that there is an imminent hazard to health, revocation of approval will become effective immediately and any administrative procedures will be expedited.

(5) A treatment program or medication unit or any part thereof, including any facility or any individual, may appeal to the Food and Drug Administration a complete or partial denial or revocation of approval by the State authority unless the denial or revocation is based upon a State law or regulation. The appeal shall first be made to the Director of the Division of Methadone Monitoring who shall hold an informal conference on the matter in accordance with paragraph (h)(2) of this section. The

State authority may participate in the conference. The appellant or the State authority may appeal the decision of the Director, Division of Methadone Monitoring, to the Director of the Bureau of Drugs. If the Director of the Bureau of Drugs proposes to deny or revoke approval, such action shall be handled in accordance with paragraph (h)(3) of this section. The Director of the Bureau of Drugs may not grant or retain Food and Drug Administration approval if he finds that the appellant is not in compliance with all applicable State laws and regulations and with this section.

(6) Upon revocation of approval of an application, the Director of the Bureau of Drugs will notify the applicant, the State authority, the Drug Enforcement Administration, Department of Justice, and all other appropriate persons that the applicant may no longer receive shipments of methadone, and will require the recall of all methadone from the applicant. Revocation of approval may also result in criminal prosecution.

* * * * *

(l) Notice of opportunity for hearing; notice of appearance and request for hearing; grant or denial of hearing. (1) The notice to the applicant of an opportunity for a hearing on a proposal by the Director of the Bureau of Drugs to deny or revoke approval of an application to receive shipments of methadone (Forms FD-2632 "Application for Approval of Use of Methadone in a Treatment Program" and FD-2636 "Hospital Request for Methadone for Analgesia in Severe Pain and for Detoxification and Maintenance Treatment") will state the reasons for the Director's action and the grounds upon which he proposes to issue his order.

(i) Such notice shall be specific, i.e., either referring to specific requirements in the statute and regulations with which there is a lack of compliance, or providing a detailed description and analysis of the specific facts resulting in the notice.

(ii) The notice will be published in the FEDERAL REGISTER and will state that the applicant has 30 days after the date of publication of the notice within which he is required to file a written notice of appearance and request for hearing if he elects to avail himself of the opportunity for a hearing. The failure to file such a written notice of appearance and request for hearing within that 30 days constitutes an election by the applicant not to avail himself of the opportunity for a hearing.

(2) The notice of opportunity for hearing shall be provided to an applicant by delivering the notice in person or by sending it by registered or certified mail to the last address shown in the application to receive shipments of methadone.

(3)(i) If the applicant elects to avail himself of the opportunity for hearing, he shall file with the Hearing Clerk within 30 days after the date of the publication of the notice of opportunity for hearing (a) a written notice of appearance and request for hearing, and (b) unless a different period of time is specified in the notice of opportunity for hearing, the records, data, and information on which he relies to justify a hearing with respect to his application to receive shipments of methadone.

(ii) No records, data, or information submitted after such 30 days will be considered in determining whether a hearing is warranted. Exceptions may be made on the basis of a showing of inadvertent omission and hardship.

(iii) Any other interested person who is not subject to the notice of opportunity for hearing may also submit comments on the proposal to deny or revoke approval of the application to receive methadone shipments. Such comments shall be submitted within the time, and pursuant to the requirements, specified in this section.

(4) The failure of any person subject to a notice of opportunity for hearing to submit a notice of appearance and request for hearing or to raise all contentions on which he relies shall constitute a waiver of any such contentions not so raised.

(5) Upon receipt of any request for hearing, the Director of the Bureau of Drugs shall prepare an analysis of the request and a proposed order ruling upon the matter. The analysis and proposed order, the request for hearing, and any proposed order denying a hearing and response pursuant to paragraph (1)(6)(ii) of this section, shall be submitted to the office of the Commissioner for independent review and decision. No representative of the Bureau of Drugs shall participate or advise in the review and decision by the Commissioner. The office of the General Counsel shall observe the same separation of functions.

(6) A request for hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine

and substantial issue of fact that requires a hearing with respect to the particular application specified in the request for hearing.

(i) A specific notice of opportunity for hearing (as defined in paragraph (l)(l)(i) of this section) shall state that, if it conclusively appears from the face of the records, data, and information in the request for hearing that there is no genuine and substantial issue of fact which precludes the denial of approval of the application or the revocation of approval of the application, the Commissioner will enter summary judgment against the person(s) who requests a hearing, making findings and conclusions and denying a hearing. Any such order entering summary judgment shall set forth in detail the findings and conclusions of the Commissioner and shall specify why the applicant fails to meet the requirements of the statute and regulations or why the request for hearing does not raise a genuine and substantial issue of fact.

(ii) Where the person(s) requesting a hearing submits records, data, or information of a type required by the statute and regulations, and the Director of the Bureau of Drugs concludes that summary judgment against such person(s) should be considered, he shall serve upon such person(s) by registered mail a proposed order denying a hearing. Such person(s) shall have 30 days after receipt of such proposed order to respond with sufficient records, data, and information to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing.

(iii) If review of the records, data, and information submitted warrants the conclusion that the ground(s) cited in the notice are not valid, the Commissioner shall deny the hearing, enter summary judgment for the person(s) requesting the hearing, and rescind the notice of opportunity for hearing.

(iv) In the case of denial or revocation of approval, if a hearing is requested and justified, it shall commence no more than 90 days after the expiration of such 30 days (the period within which the request for a hearing and all filings must be made pursuant to paragraph (l)(l)(ii) of this section).

(v) A hearing shall be granted if there exists a genuine and substantial issue of fact or if the Commissioner concludes, in his discretion, that a hearing would otherwise be in the public interest.

(vi) A request for hearing, and any subsequent grant or denial of a hearing, shall be applicable only to the particular methadone program named in such documents.

(7) Any application to receive methadone shipments subject to a notice of opportunity for hearing, for which an opportunity for a hearing is waived or for which a hearing is denied, shall promptly be the subject of a notice published in the FEDERAL REGISTER denying or revoking approval of the application. The Commissioner may, in his discretion, defer or stay such action pending a ruling on any related request for a hearing or pending any related hearing or other administrative or judicial proceeding.

Interested persons may, on or before (insert date 60 days after date of publication in the FEDERAL REGISTER), submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: OCT 7 1975.

Sam D. Fine
Associate Commissioner for
Compliance.

CERTIFIED COPY ORIGINAL

Lola E Snyder